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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/543,004	10/11/2006	Martial Ruat	1169-038	2440

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EXAMINER	
SZNAIDMAN, MARCOS L	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
04/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/543,004	RUAT ET AL.	
	Examiner	Art Unit	
	MARCOS SZNAIDMAN	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-38* is/are pending in the application.

4a) Of the above claim(s) *26,36 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-25,27-35 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2 pages / 07/22/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to applicant's reply filed on January 21, 2009.

Election/Restrictions

Applicant's election of Group I (Claims 16-35 and 38) and mifepristone (RU 486 or 17-beta-hydroxy-11-beta-(4-dimethylaminophenyl)-17alpha-(prop-1-ynyl)-estra-4,9-dien-3-one) as the elected species in the reply filed on January 21, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a).

Status of Claims

Claims 16-38 are currently pending and are the subject of this office action.

Claims 26 and 36-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 21, 2009.

Claims 16-25, 27-35 and 38 are presently under examination.

Priority

The present application is a 371 of PCT/FR04/00151 filed on 01/22/2004, and claims priority to foreign application: FRANCE 03 00646 filed on 01/22/2003.

Information Disclosure Statement

The Information Disclosure Statement filed on July 22 2005 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy of the IDS is attached hereto.

Claim Objections

Claim 27 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 27, further limits claim 26 "wherein Z1 and Z2 each independently represents a C1-C4 alkyl radical". However, claim 26 which specifically identifies what R1. As such, it is not clear how claim 27 further limits claim 26.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 recites the limitation "wherein Z1 and Z2 is each methyl". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims16-25, 27-33 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Haak et. al. (The Lancet (1990) 336:124-125, cited by Applicant).

Claims 16-25, 27-31 and 38, recite a method for modulating a Hedgehog protein signaling pathway in a mammal, which comprises administering to the mammal an effective amount of mifepristone (species elected).

For claims 16-25, 27-31 and 38, Haak teaches a method of treating meningioma (a type of nervous tissue tumor) comprising administering to the patient an oral dose of mifepristone (see page 125 left column, first paragraph).

While Haak does not teach "modulating a Hedgehog protein signaling pathway", the recitation has not been given patentable weight because the recitation occurs in the

preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In other words, what is claimed is "a method comprising administering to a mammal an effective amount of mifepristone". And this is clearly and explicitly anticipated by Haak et. al.

Alternatively, even if one were to give some weight to the preamble: the phrase "for modulating a Hedgehog protein signaling pathway" is considered an inherent property of the method of Haak because the same composition (mifepristone) is administered to the same population (individuals with same type of cancer, like meningioma). In other words, products of identical or similar composition cannot exert mutually exclusive properties when administered under the same circumstances. MPEP 2112 I states: "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer".

Claims 32 and 33, further limit claim 16, wherein the method effects treatment of tumors linked to hyperactivation of the Hedgehog pathway (meningiomas in claim 33).

As discussed above, Haak further teaches a method of treating meningioma (a type of nervous tissue tumor) comprising administering to the patient an oral dose of mifepristone (see page 125 left column, first paragraph).

Claims 16-25, 27-31, 34 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Reiner et. al. (WO 98/48784, cited by Applicant).

Claim 34 further limits claim 16, wherein the method effects treatment of neurodegenerative (-type) pathologies.

For claims 16-25, 27-31, 34 and 38 Reiner teaches a method of treating Alzheimer's disease (a neurodegenerative (-type) pathology) comprising administering RU-486 (mifepristone) (see claims 24-29).

While Reiner does not teach "modulating a Hedgehog protein signaling pathway", the recitation has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In other words, what is claimed is "a method comprising administering to a mammal an effective amount of mifepristone, wherein the method

effects treatment of a neurodegenerative (-type) pathology". And this is clearly and explicitly anticipated by Reiner.

Alternatively, even if one were to give some weight to the preamble: the phrase "for modulating a Hedgehog protein signaling pathway" is considered an inherent property of the method of Reiner because the same composition (mifepristone) is administered to the same population (individuals with a neurodegenerative (-type) pathology, like Alzheimer's). In other words, products of identical or similar composition cannot exert mutually exclusive properties when administered under the same circumstances. MPEP 2112 I states: "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer".

Claims 16-25, 27-31 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Gettys et. al. (International Journal of Obesity (1997) 21:865-873, cited by Applicant).

Claim 35, further limits claim 16, wherein the method effects treatment of diabetes.

For claims 16-25, 27-31 and 35, Gettys teaches a method of treating diabetes comprising administering mifepristone (see title and abstract).

While Gettys does not teach "modulating a Hedgehog protein signaling pathway", the recitation has not been given patentable weight because the recitation occurs in the

preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In other words, what is claimed is "a method comprising administering to a mammal an effective amount of mifepristone, wherein the method effects treatment of diabetes". And this is clearly and explicitly anticipated by Gettys.

Alternatively, even if one were to give some weight to the preamble: the phrase "for modulating a Hedgehog protein signaling pathway" is considered an inherent property of the method of Gettys because the same composition (mifepristone) is administered to the same population (individuals with diabetes). In other words, products of identical or similar composition cannot exert mutually exclusive properties when administered under the same circumstances. MPEP 2112 I states: "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer".

Conclusion

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/
Examiner, Art Unit 1612
March 30, 2009.

/Brandon J Fetterolf/

Primary Examiner, Art Unit 1642